**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF TEXAS**
**FORT WORTH DIVISION**

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| OUTSOURCING FACILITIES ASSOCIATION, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,<br><br>Defendants<br><br>and<br><br>NOVO NORDISK INC.,<br><br>Intervenor-Defendant | Case No. 4:25-cv-00174-P |

**REPLY BRIEF IN SUPPORT OF**
**INTERVENOR-DEFENDANT NOVO NORDISK INC.'S**
**MOTION FOR SUMMARY JUDGMENT**

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## INTRODUCTION

Plaintiffs' opposition to Novo Nordisk's Motion for Summary Judgment mischaracterizes the record, misapprehends the standard of review, and recycles arguments that this Court has already considered and correctly rejected. This Court should deny Plaintiffs' motion and enter judgment for Defendants.

## ARGUMENT

### I. FDA Reasonably Determined that the Semaglutide Injection Shortage Had Ended.

#### A. Plaintiffs misrepresent the record regarding "compounding supply."

Plaintiffs contend that the "decision failed to account for compounding supply." (Pls.' Opp. (ECF No. 78), at 1 (capitalization omitted)). But FDA's Decision Memorandum addressed compounding volume at length. (*See* FDA 000041–46).[1] Accordingly, Plaintiffs' assertion that FDA failed to consider an "obvious" topic is wrong.

Plaintiffs complain that FDA failed to "mention … Novo Nordisk's estimate that compounded semaglutide satisfied about 20% of the market." (Pls.' Opp. at 1). As Novo Nordisk and FDA have both explained, that was *not* Novo Nordisk's estimate, but rather an unsubstantiated estimate from an unreliable internet article; and it was not about Wegovy® or Ozempic® specifically, but about all GLP-1 products. (*See* FDA 000262; *see also* NNI Opp. (ECF No. 80), at 3–6; FDA Opp. (ECF No. 79), at 4–6). Plaintiffs further misrepresent the record in stating that "Novo Nordisk admitted [redacted]." (Pls.' Opp. at 2). In fact, Novo Nordisk reported that [redacted]—that is, by the time that [redacted]

[1] All citations to "(FDA 00----)" are to the Administrative Record filed with the Court (ECF No. 49); copies of cited pages not already submitted in Novo Nordisk's previous Appendices (ECF Nos. 74 and 81) are submitted as a Supplemental Appendix to this brief.

[redacted] as to compounders of semaglutide products. (*See* NNI Opp. at 5; FDA 000391). In other words, even accepting the flawed 20% estimate and a highly unlikely 1:1 transitional demand (*but see* FDA 000045), [redacted].

Plaintiffs also complain that FDA failed to mention "OFA's estimate that [compounded semaglutide] satisfied over 50% of the market." (Pls.' Opp. at 1). But OFA provided no basis whatsoever for that assertion, which contrasted starkly with the actual data submitted to FDA by 503B compounders—as required by 21 U.S.C. § 353b(b)(2) (*see* FDA 000042 n.139)—showing an average of 310,000 packages of compounded semaglutide per month. (FDA 000044). Given that OFA's 50% "estimate" was nothing but *ipse dixit* unsupported by *any* data or other record evidence, the APA did not require FDA to mention it specifically in the agency's Delisting Action. *See Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993) (no APA requirement to address speculative comments). Nor does Plaintiffs' lead case on this score—*10 Ring Precision, Inc. v. Jones*—suggest otherwise. 722 F.3d 711 (5th Cir. 2011). *10 Ring* confirms that when an agency chooses between multiple *policy* alternatives, it "must consider only significant and viable and obvious alternatives." *Id*. at 724 (citation omitted). Here, the agency's analysis on this point did not involve a policy choice, but in any event, OFA's unsubstantiated estimate was not "viable."

The Administrative Record confirms that, rather than accepting unsubstantiated and self-serving assertions of compounding volume at face value, FDA focused on the substantiated numerical data before it. Specifically, FDA estimated that compounders were filling 520,000 prescriptions for compounded semaglutide injection each month based on statutorily-required reports submitted directly by 503B outsourcing facilities and pharmacy-level dispensing data from [redacted] provided by a trade association with 503A pharmacy members. (*See* FDA 000041–46; FDA 001101–03). This was FDA's choice to make. *See Outsourcing Facilities*

*Ass'n v. FDA*, No. 4:24-CV-0953-P, 2025 WL 746028, at *13 (N.D. Tex. Mar. 5, 2025) ("*OFA I*") (FDA may give "more weight to specific, reliable, comprehensive, and current information.").[2]

At bottom, Plaintiffs misrepresent FDA's approach to assessing transitional demand. Plaintiffs say that FDA "require[d] Novo Nordisk to show that it could satisfy market demand currently being satisfied by compounders" "by applying a one-for-one metric in measuring how much Novo Nordisk's supply would need to increase." (Pls.' Opp. at 2). But FDA actually determined that "it is not reasonable to project that demand for compounded products will materialize in the future as one-for-one demand for Novo Nordisk's approved products." (FDA 000045). Among other reasons, FDA noted that "compounded products are in some cases promoted for uses that differ from the labeled indications of the approved drugs" and observed that "an unknown quantity of compounded semaglutide products have differences in formulation from the approved drug." (*Id.*). In short, the agency clearly considered and adequately addressed the issue of "transitional demand" in its decision. (*See, e.g.*, FDA 000046 ("Taking the available information together, while we recognize that significant compounding of semaglutide injection products is occurring, and that some patients currently receiving those products can be expected to seek Novo Nordisk's approved products at a future point when compounding is curtailed, based on our best judgment and looking at the available information with its limitations, we conclude that Novo Nordisk's supply will meet or exceed projected demand.")). FDA's thorough analysis certainly did not fall short of the APA's requirements.

[2] Plaintiffs say that FDA understood the 503A trade association figures on compounded demand to be "only a small portion" of some "exponentially higher" total. (Pls.' Opp. at 3). But the quoted language comes not from FDA, but rather from the trade association itself. (FDA 000044; *see* FDA 001101–03). For its part, FDA concluded that the association "ha[d] *not* provided information that would" support a higher estimate. (FDA 000045 (emphasis added)).

**B. Plaintiffs misconstrue the CEO remarks.**

Plaintiffs accuse FDA of failing "to consider significant evidence" in the form of early November 2024 remarks from Novo Nordisk's CEO and the CEO of Cardinal Health. (Pls.' Opp. at 3). But, FDA "reviewed various articles and blog posts submitted by various groups, as well as other news coverage." (FDA 000040). Those submissions included the statements attributed to the CEOs which were included in the administrative record, (*see* FDA 000636–637; FDA 000693–695), demonstrating that the agency considered the statements in reaching its decision. *See City of Dallas v. Hall*, Nos. 3:07-CV-0060-P, 3:07-CV-0213-P, 2007 WL 3257188, at *4 (N.D. Tex. Oct. 29, 2007) (explaining that "the designation of the administrative record, like any established administrative procedure, is entitled to a presumption of administrative regularity" (citing *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 740 (10th Cir. 1993))). Further, as Novo Nordisk explained, FDA specifically flagged Novo Nordisk's CEO's remarks in its correspondence with Novo Nordisk. (FDA 000262). It is not true that FDA failed to "consider" this evidence. Plaintiffs may disagree with FDA's assessment on this point, but they cannot truthfully contend that FDA failed to consider the very statements that the Administrative Record confirms FDA did consider. (*See, e.g.*, FDA 000262 (FDA asking Novo Nordisk about the CEO statements); *see also* NNI Opp. at 6–9). In fact, FDA was consistent in its methodological approach—crediting substantiated data over stray remarks and anecdotal evidence. *See supra* Section I.A (discussing treatment of news article); *infra* Section I.D (discussing treatment of anecdotal reports). Regardless, FDA need not "discuss every item of fact or opinion included in the submissions" it receives, so the fact that FDA did not call out the CEO statements in its Delisting Action does not defeat FDA's reasonable analysis and decision not to credit otherwise less probative evidence. *Pub. Citizen, Inc.*, 988 F.2d at 197.

**C. Plaintiffs' criticisms of Novo Nordisk's data are unavailing.**

Plaintiffs' efforts to discredit Novo Nordisk's comprehensive data submissions to FDA rely on arguments that this Court has already considered and correctly rejected.[3]

[redacted]. Plaintiffs fault FDA for considering [redacted] data when evaluating demand, alleging that it is a "circular" definition, going so far as to say that FDA "admitted error" in relying on that data. (Pls.' Opp. at 4). As Defendants have repeatedly explained, FDA did not "admit error" in relying on [redacted], but recognized the limitations inherent in this particular demand metric, which is why FDA did not rely on that data "standing alone." (*See* FDA 000030; *see also* NNI Opp. at 9–10; FDA Opp. at 7–8; FDA PI Opp. (ECF. No. 51) at 12–13).

Instead, FDA considered other data to confirm that the shortage was over. (*See* NNI Br. (ECF No. 73) at 10; FDA Br. (ECF No. 69) at 9–12). Contrary to Plaintiffs' assertion, those other data sources were relevant to *both* supply *and* demand. Regarding supply, FDA noted that Novo Nordisk reported inventory of [redacted] semaglutide injection medicines in its most recent reports and had a [redacted]. (FDA 000044–45). As to demand, FDA considered order volume from wholesalers and other customers, including certain pharmacies, and other volume related to direct patient assistance, noting Novo Nordisk [redacted]. (FDA 000023; *see* FDA 000022). FDA also observed that when Novo Nordisk [redacted]—indicating that demand was saturated. (FDA 000024).

[3] Plaintiffs cite *Chamber of Commerce v. Department of Labor*, 885 F.3d 360, 382 (5th Cir. 2018), for the proposition that FDA took Novo Nordisk's "'inconsistent' explanations at face value while discarding all evidence of a shortage." (Pls.' Opp. at 1). But that case faulted the Department of Labor for applying a rule that conflicted with the plain text of the Employee Retirement Income Security Act. *Chamber of Com.*, 885 F.3d at 369. That is irrelevant to the FDA's consideration of evidence under the FDCA.

*Inventory.* Plaintiffs assert that average inventory is an "undefined" and "unhelpful" measure. (Pls.' Opp. at 5). But the record confirms a clear definition: "the amount of finished product on average in a given month maintained in stock after all open orders from customers have been filled." (FDA 000019). As this Court has already observed, average net inventory avoids any concerns about "triple-count[ing]" supply, and it was not unreasonable for the agency to rely on this data. *See Outsourcing Facilities Ass'n v. FDA*, No. 4:25-CV-0174-P, 2025 WL 1239727, at *6 (N.D. Tex. Apr. 24, 2025) ("*OFA II*").

Plaintiffs criticize FDA's citation to Table 1 that includes a "snapshot" of net inventory [redacted], accusing Novo Nordisk of "select[ing] a particularly favorable moment" in its data. (Pls.' Opp. at 5). But the date chosen was not arbitrary or self-serving; rather, it was the most recent net inventory data in Novo Nordisk's possession (and specifically requested by FDA), [redacted]. (*See* FDA 000420). And Defendants have addressed conclusively Plaintiffs' arguments regarding days-on-hand data in prior briefing. (*See* NNI Opp. at 11–12; FDA Opp. at 9).

[redacted]. Plaintiffs' arguments regarding [redacted] make the same mistaken assumptions regarding Table 2 that this Court previously addressed. *See OFA II*, 2025 WL 1239727, at *6. Plaintiffs question why "[redacted]" do not "translate" one-to-one into "[redacted]." (Pls.' Opp. at 6.) Once again, Plaintiffs fail to recognize that [redacted] Table 2 is *net* inventory—stock remaining after all open orders from customers have been filled. (*Id.*). [redacted] not encapsulated in Table 2. (*See* FDA 000423 (explaining the [redacted])).

Plaintiffs also point to screenshots [redacted] that allegedly showed wholesalers with restricted stock of Novo Nordisk's semaglutide injection products. (Pls.' Opp. at 6 (citing Pls.' PI App. (ECF No. 39-1) at 238–48)). But, as this Court has determined, it was reasonable for FDA to credit objective data over these anecdotal screenshots. *See OFA II*, 2025 WL 1239727, at *8. And the screenshots certainly do not render FDA's consideration of [redacted] as available supply unreasonable.

*Wholesaler Supply.* Nothing in Plaintiffs' briefing renders FDA's consideration of Novo Nordisk's [redacted] unreasonable. *See OFA II*, 2025 WL 1239727, at *5; (*see also* NNI Opp. at 7–9; FDA Opp. at 7). Plaintiffs ignore that Novo Nordisk had sufficient [redacted]. (FDA 000020; FDA 000029). Plaintiffs aver that it is "meaningless" that [redacted]. (Pls.' Opp. at 7). But obviously it was reasonable for FDA to consider that fact—along with many other data points—when making its shortage determination, because stock levels are indisputably probative to the agency's shortage determination. *See OFA II*, 2025 WL 1239727, at *8. In any event, it is undisputed that [redacted].

*Projected Supply and Demand.* Plaintiffs repeat criticisms of FDA's handling of projected supply and demand. (*See* Pls.' Opp. at 8). Again, FDA credited Novo Nordisk's explanation regarding [redacted]. *See OFA II*, 2025 WL 1239727, at *5; (*see also* NNI Opp. at 7–9; FDA Opp. at 7). And FDA was not required to account for Plaintiffs' unreliable and unsubstantiated 20% and 50% compounder demand figures when estimating projected demand. *See supra* Section I.A.

*Time Period.* Plaintiffs argue that FDA chose "differing time periods for analyzing comparable drugs," referring to FDA's tirzepatide shortage decision. (Pls.' Opp. at 9). But as this Court has explained, "[t]he statutory scheme provides the FDA with the discretion to determine the relevant time period," including as it relates to differently-situated drugs. *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-CV-0953-P, 2025 WL 1397537, at *3 (N.D. Tex. May 13, 2025) ("*OFA III*"). This reasoning applies equally to the argument that "[redacted]." (Pls.' Opp. at 6). And FDA's reliance on "[redacted]" in considering whether a shortage existed (FDA 000019 n.20), "is consistent with Congress's mandate." *OFA III*, 2025 WL 1397537, at *3.

**D. FDA considered and appropriately dismissed unreliable evidence.**

Plaintiffs continue to protest the agency's decision to credit hard data over unreliable, anecdotal evidence. (Pls.' Opp. at 9–10). But this Court correctly found that FDA's approach was reasonable. *OFA II*, 2025 WL 1239727, at *8. Plaintiffs argue that the agency "miss[ed] the forest for the trees" because the compounding industry submitted a large "volume" of documents. (Pls.' Opp. at 10). But unreliable evidence does not become reliable simply because there is *more* of it. Plaintiffs also accuse FDA of "parsing each piece of evidence," whatever that means. (*Id.*). But the record is clear that FDA considered all the evidence before it, for both what it showed and its limitations, in coming to its decision. This is precisely what the APA requires. *See, e.g.*, *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962) (to satisfy APA, agency must make a "rational connection between the facts found and the choice made").[4]

[4] In accusing FDA of engaging in "handwaving dismissal" of "non-Novo Nordisk evidence," Plaintiffs cite *Sutter East Bay Hospitals v. NLRB*, 687 F.3d 424, 437 (D.C. Cir. 2012). (Pls.' Opp. at 9). That inapposite case involved a review of a labor-relations disciplinary action under a different standard. *See Sutter E. Bay*, 687 F.3d at 434. More importantly, in marked contrast to the ALJ's decision in *Sutter East Bay*, FDA explained in its decision why it gave more weight to some evidence than to other submissions. (*See, e.g.*, FDA 000018–46).

## II. FDA Applied the Correct Statutory Framework.

Plaintiffs argue that compounded drugs should be counted as part of demand but *not* as part of supply, asserting that the "statutory question presented" is whether the "manufacturer alone" can satisfy demand for *both* the FDA-approved drug product *and* all compounded versions of those products. (Pls.' Opp. at 10). The statutory text contradicts that argument. The statutory definition of shortage is "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." 21 U.S.C. § 356c(h)(2). It is clear from that definition that the same "the drug" informs both the "supply" and "demand" sides of the equation, and Plaintiffs offer no credible reading to the contrary. This Court correctly determined the first time that "FDA must base its shortage determination on … 'the drug' listed on the shortage list," and not on demand for compounded drugs. *OFA III*, 2025 WL 1397537, at *5.

Plaintiffs also argue that the "definition of shortage is inconsistent with requiring a 'national' failure of supply to meet demand," contending that regional shortages also fall under the FDCA's definition of a "shortage." (Pls.' Opp. at 11). But this Court has determined that "it was not unreasonable for the FDA to conclude that some localized shipping delays are not evidence of a nationwide shortage." *OFA III*, 2025 WL 1397537, at *4. FDA's reading is also logical; as the Court reasoned, "if [Novo Nordisk] was only supplying regions A and B because it lacked the ability to also supply region C, then that fact would become evident in the FDA's review of the nationwide data." *Id.* FDA's interpretation of the FDCA focused on "drug shortages on a *national* level" remains "the best reading of the statute" because "FDA is a national agency and must therefore consider drug shortages on a national level." *Id.* at *3–4 (emphasis added).

Finally, Plaintiffs argue that "the agency must consider shipping delays as part of its shortage analysis" because shipping delays are part of an enumerated list the FDCA provides as potential reasons for FDA's shortage determination. (Pls.' Opp. at 11 (citing 21 U.S.C.

§ 356e(b)(F))). But the Court has already rejected that argument, noting that "the statute does not mandate or even recommend that the FDA must or should consider all of the enumerated categories when making a shortage determination." *OFA III*, 2025 WL 1397537, at *4. In any event, as Plaintiffs concede, the agency considered shipping delays. (*See* Pls.' Opp. at 12 (noting that FDA "concluded shipping delays were relevant if they were 'so significant as to affect supply on a nationwide level'" (quoting FDA 000039))).

**III. FDA Did Not Abuse Its Discretion in Proceeding by Adjudication.**

Plaintiffs offer nothing new to support their notice-and-comment claim. (*See* Pls.' Opp. at 12–14). This Court has rejected those notice-and-comment arguments three times. *See, e.g.*, *OFA III*, 2025 WL 1397537, at *2.

Plaintiffs again rely on *Safari Club International v. Zinke*, 878 F.3d 316 (D.C. Cir. 2017), which the Court has cogently distinguished. *See OFA I*, 2025 WL 746028, at *7–8. Plaintiffs also resort to a straw man, criticizing Novo Nordisk and FDA for failing to argue that the statute's "up-to-date" requirement and confidentiality provisions "expressly superseded" the APA's rulemaking provisions. (Pls.' Opp. at 13). But that was never the point. Because "the Delisting Action is not a rule," *OFA III*, 2025 WL 1397537, at *2, those reasons merely show that FDA did not abuse its discretion by proceeding through adjudication, (*see* NNI Opp. at 16–17); *OFA I*, 2025 WL 746028, at *4–5 (relying on these considerations solely to address FDA's discretion). Plaintiffs also nitpick the Court's observation in *OFA I* that their notice-and-comment argument poses a "Catch-22." (Pls.' Opp. at 12); *see OFA I*, 2025 WL 746028, at *6. But they concede the fundamental point—the APA directs that the process required to remove a drug from the shortage list must also be the process used to add it. (*See* Pls.' Opp. at 12).

## CONCLUSION

This Court should deny Plaintiffs' motion for summary judgment and grant Defendants' motions for summary judgment.

Respectfully submitted,

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June 11, 2025

**CERTIFICATE OF SERVICE**

I hereby certify that, on June 18, 2025, I caused the foregoing document to be filed with the Clerk of the Court of the United States District Court for the Northern District of Texas using the Court's CM/ECF system.

*/s/ Trevor Carolan*
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